

Food and Drug Administration, HHS

§ 201.127

(c) This exemption shall not apply to any substance intended for use in compounding which results in a new drug, unless an approved new-drug application covers such use of the drug in compounding prescriptions.

[40 FR 13998, Mar. 27, 1975, as amended at 67 FR 4906, Feb. 1, 2002]

§ 201.122 Drugs for processing, repackaging, or manufacturing.

A drug in a bulk package, except tablets, capsules, or other dosage unit forms, intended for processing, repackaging, or use in the manufacture of another drug shall be exempt from section 502(f)(1) of the act if its label bears the statement "Caution: For manufacturing, processing, or repackaging"; and if in substantially all dosage forms in which it may be dispensed it is subject to section 503(b)(1) of the act, the statement "Rx only", or if in substantially all dosage forms in which it may be dispensed it is subject to section 503(f)(1) of the act, the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian". This exemption and the exemption under § 201.120 may be claimed for the same article. However, the exemption shall not apply to a substance intended for a use in manufacture, processing, or repackaging which causes the finished article to be a new drug or new animal drug, unless:

(a) An approved new drug application or new animal drug application or a new animal drug index listing covers the production and delivery of the drug substance to the application or index listing holder by persons named in the application or in the request for determination of eligibility for indexing, and, for a new drug substance, the export of it by such persons under § 314.410 of this chapter; or

(b) If no application is approved with respect to such new drug or new animal drug, and it is not listed in the index, the label statement "Caution: For manufacturing, processing, or repackaging" is immediately supplemented by the words "in the preparation of a new drug or new animal drug limited by Federal law to investigational use", and the delivery is made for use only in the manufacture of such new drug or new animal drug limited to investiga-

tional use as provided in part 312 or § 511.1 or § 516.125 of this chapter; or

(c) A new drug application or new animal drug application or a request for addition to the index covering the use of the drug substance in the production and marketing of a finished drug product has been submitted but not yet approved, disapproved, granted, or denied, the bulk drug is not exported, and the finished drug product is not further distributed after it is manufactured until after the new drug application or new animal drug application is approved or the request for addition to the index is granted.

[41 FR 6911, Feb. 13, 1976, as amended at 41 FR 15844, Apr. 15, 1976; 50 FR 7492, Feb. 22, 1985; 55 FR 11576, Mar. 29, 1990; 57 FR 54301, Nov. 18, 1992; 67 FR 4906, Feb. 1, 2002; 72 FR 69119, Dec. 6, 2007]

§ 201.125 Drugs for use in teaching, law enforcement, research, and analysis.

A drug subject to § 201.100 or § 201.105, shall be exempt from section 502(f)(1) of the act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing.

[41 FR 6911, Feb. 13, 1976]

§ 201.127 Drugs; expiration of exemptions.

(a) If a shipment or delivery, or any part thereof, of a drug which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such shipment or delivery or part thereof, at the beginning of that shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such drug being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device.

(b) The exemptions conferred by §§ 201.117, 201.119, 201.120, 201.122, and

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201.125 shall continue until the drugs are used for the purposes for which they are exempted, or until they are relabeled to comply with section 502(f)(1) of the act. If, however, the drug is converted, compounded, or manufactured into a dosage form limited to prescription dispensing, no exemption shall thereafter apply to the article unless the dosage form is labeled as required by section 503(b) and §§ 201.100 or 201.105.

[41 FR 6911, Feb. 13, 1976]

§ 201.128 Meaning of “intended uses”.

The words *intended uses* or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, and 201.122 refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

[41 FR 6911, Feb. 13, 1976]

21 CFR Ch. I (4–1–12 Edition)

§ 201.129 Drugs; exemption for radioactive drugs for research use.

A radioactive drug intended for administration to human research subjects during the course of a research project intended to obtain basic research information regarding metabolism (including kinetics, distribution, and localization) of a radioactively labeled drug or regarding human physiology, pathophysiology, or biochemistry (but not intended for immediate therapeutic, diagnostic, or similar purposes), under the conditions set forth in § 361.1 of this chapter, shall be exempt from section 502(f)(1) of the act if the packaging, label, and labeling are in compliance with § 361.1(f) of this chapter.

[41 FR 6911, Feb. 13, 1976]

Subpart E—Other Exemptions

§ 201.150 Drugs; processing, labeling, or repacking.

(a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a drug which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501(b) and 502 (b), (d), (e), (f), and (g) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug in such establishment as will insure, if such specifications are followed, that such drug will not be adulterated or misbranded within the meaning of the act